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In the Supreme Court of the United States

1958

MARSHALL S. FINE, CHIEFMAN OF HEALTH INSULATION  
AND WILFRED FINE

FLORIDA CITIZEN BENJAMIN FRANKLIN SCHILL, ET AL

PETITION FOR A WRIT OF HABEAS CORPUS OF THE UNITED STATES  
COURT OF APPEALS FOR THE FIFTH CIRCUIT

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# In the Supreme Court of the United States

OCTOBER TERM, 1957

No.—

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION  
AND WELFARE, PETITIONER

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES  
COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Solicitor General, on behalf of Marion B. Folsom, Secretary of Health, Education, and Welfare, prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit, entered in the above cases on July 12, 1957.

## OPINIONS BELOW

The Secretary's order (R. 281) appears in 20 F. R. 8493. The opinions in the Court of Appeals, printed in the Appendix, *infra*, pp. 25-52, are reported in 246 F. 2d 850.

## JURISDICTION

The judgments of the Court of Appeals were entered on July 12, 1957 (Appendix, *infra*, pp. 52-53). A motion for rehearing before the court *en banc* was denied on August 28, 1957, Chief Judge Hutcheson



dissenting (Appendix, *infra*, p. 54). On November 27, 1957, by order of Justice Black, the time for filing a petition for a writ of certiorari was extended to and including January 3, 1958. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1) and 21 U. S. C. 371 (f) (4).

#### QUESTIONS PRESENTED

1. Whether the court below erred in directing the Secretary of Health, Education, and Welfare to certify as harmless for use in the coloring of oranges a coal-tar color which admittedly has been properly found to be poisonous and properly decertified for general use under Section 406 (b) of the Federal Food, Drug, and Cosmetic Act.

2. Whether the provisions of Section 406 (a) authorizing the Secretary to establish tolerances for use of deleterious substances in food, when required in production, applies to coal-tar colors found not to be harmless under Section 406 (b).

3. Whether "required in the production," as used in Section 406 (a), means required in post-harvest treatment of oranges for greater eye-appeal in the market place.

4. Whether, assuming that the Secretary has power to establish tolerances for use of poisonous coal-tar color in oranges, it was proper for the Court of Appeals to assume that *prima facie* the coloring for oranges was required for production, and not dangerous in the particular use, and to cast the burden on the Secretary to show that such use was dangerous.

## STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, as amended, 52 Stat. 1040, 70 Stat. 512 (21 U. S. C. 301, *et seq.*), provides in pertinent part as follows:

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; \* \* \*

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406 \* \* \* *Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination") the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to

4

March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." [21 U. S. C. 342].

\* \* \* \* \*

SEC. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). \* \* \* In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents [21 U. S. C. 346].

\* \* \* \* \*

SEC. 701 (f) (1). In a case of actual controversy as to the validity of any order under sub-

section (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the nineteenth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order \* \* \*

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. \* \* \* The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari \* \* \* " [21 U. S. C. 371].

#### STATEMENT

The Secretary of Health, Education, and Welfare, after public proceedings and on the basis of uncontroverted evidence, issued a final order on November 10, 1955, removing coal-tar colors FD&C Orange No. 1, Orange No. 2, and Red No. 32 from the approved list of harmless colors for unrestricted use in food, drugs, and cosmetics (R. 281). This order was reviewed generally and upheld by the Second Circuit (*Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F. 2d 866), and was reviewed and held invalid, insofar as it concerns Red. No. 32 as used for coloring oranges in Texas and



Florida, by the court below in this case. The pertinent facts are as follows:

1. Red 32 had been placed on the approved list in 1939, after a public hearing at which its harmlessness was apparently established. New investigations by the Department of Health, Education, and Welfare were initiated after scientific questions as to the possible carcinogenicity of Red 32 and other coal-tar colors were raised. These investigations were spurred by the Hearings before a Select Committee of the House of Representatives to Investigate the use of Chemicals in Food Products.<sup>1</sup> The investigations, conducted with small laboratory animals (rats and dogs), were begun in 1951 and completed in 1953 (J. A. 54-55, 58-65, 68-84, 86-93). The result established that the three colors involved in the instant order (Red 32, Orange 1, and Orange 2) had significant toxicity.

Upon completion of the investigations, the results were given to the certified color industry (J. A. 46), and the Department announced that a hearing would be held with a view to removing Red 32 from the list of harmless colors. At the hearing, the sole scientific witness for the color industry stated that the industry had no pharmacological data of its own to present, that the industry had done no such work since 1939, and that it was "willing to accept the result of stud-

<sup>1</sup> See the opinion below, Appendix, *infra*, p. 29; *Certified Color Industry Committee v. Secretary*, 236 F. 2d 866, 867 (C. A. 2); Hearings, Select Committee, 81st Cong., 2d Sess. (pursuant to H. Res. 323), pp. 229, 238; 82d Cong., 1st Sess. (pursuant to H. Res. 74), part 1, pp. 325, 326, 332, 334; 2d Sess. (pursuant to H. Res. 74 and 447), part 3, pp. 1353-1355, 1360, 1363, 1369, 1381.



ies made by the Food and Drug Administration" (J. A. 46-49). The Florida Citrus Commission also indicated that it did not oppose "any action which the Secretary may deem advisable on the basis of the record" (J. A. 43-44).

In his order of November 10, 1955, the Secretary found that the three colors, including Red 32, are toxic, i. e., poisonous, and forbade their use on foods.

2. The court below found that the evidence justified the finding that Red 32 was toxic (Appendix, *infra*, p. 41). The detailed findings reveal that Red 32 is the most toxic of the three colors. Pharmacological studies established that at 0.5% and 0.25% in the diet of test rats (5,000 to 2,500 parts per million) the color killed most of the rats in a short time. 0.1% (1,000 ppm) had the same, but a less rapid, effect. On autopsy, the animals had liver damage, anemia, and enlargement of the right side of the heart.<sup>2</sup> In dogs, 0.04% (400 ppm) caused deterioration, weight loss, sporadic diarrhea, moderate atrophy of vital organs and muscular dystrophic changes. One dog at 0.01% (100 ppm), the lowest test dosage fed, lost weight and died. A single oral dose of 100 milligrams (about  $\frac{1}{3}$  the weight of an ordinary 5 grain aspirin tablet) produced diarrhea (R. 282, Findings 7-8).

The Secretary found the evidence inadequate to support findings as to the amounts of color likely to

<sup>2</sup> No heart damage was found in rats fed 0.25% (2,500 ppm); yet at 0.1% (1,000 ppm) heart damage was definitely shown. The pathologist remarked on the fact of the lower dosage "showing a constant effect of the dye feeding on the heart" (J. A. 80, 81).

be ingested by man from his food, drugs, and cosmetics (R. 282, Finding 10). The industry committee representative testified that his company (one of the largest in the business) had done no work to learn how much of these colors is found on various foods (J. A. 49). The Secretary concluded that, in any event, he had no statutory authority under Section 406 (b) of the Federal Food, Drug, and Cosmetic Act to list colors of established toxicity and then attempt by regulation to restrict the levels of use of the poisonous colors in selected foods, drugs, and cosmetics as a means of protecting the public from the consumption of harmful amounts of the toxic colors (R. 282, Conclusions 1-4).

3. Petitions asking the Secretary to reopen the hearing were made by the Certified Color Industry Committee (R. 259), Eli Lilly & Co. (R. 268), and Frank R. Schell (R. 209). Their purpose was to offer evidence to establish that the amounts of the three colors normally used in a variety of foods and drugs, and more particularly to establish that the amounts of Red 32 used in coloring oranges, were far below the amounts shown toxic to test animals (R. 212). The aim was to show that the amounts of color normally used are wholly insignificant from a toxicological standpoint, and at least that safe tolerances could be established for the three colors in a number of foods and drugs.

The Secretary refused to reopen (R. 211, 262-267, 277-280). His reasons were that the animal data failed to establish a safe level of dosage for the test animals; that man is more susceptible than the test animals, making it impossible to transpose the animal

data directly to man; and that Red 32 had been involved in a recent food poisoning episode, establishing the possibility that dangerous amounts would be used. The Secretary found the normal use data submitted in the petitions to reopen to be inaccurate and incomplete, the pharmacological testing inadequate to establish the extent of toxicity to a certainty that would permit him to fix safe tolerances, and that there was no statutory authority on which he could issue regulations establishing tolerances for toxic coal-tar colors.

4. The Certified Color Industry Committee sought ~~February 9, 1956 (R. 47, 48). After consolidation, the~~ Second Circuit. On August 10, 1956, that Court of Appeals affirmed the order, 236 F. 2d 866. Eli Lilly thereupon dismissed its petition for judicial review in the Seventh Circuit (C. A. 7, No. 11,682).

The present cases were filed in the Fifth Circuit on February 8, 1956 (R. 47, 48). After consolidation, the printed record was filed in February 1957. The cases were argued in May 1957, and on July 12, 1957, the Court of Appeals entered its judgment setting the order aside insofar as it removed Red 32 from the approved list of coal-tar colors that might be used on Texas and Florida oranges. The final judgment required the Secretary to certify henceforth sufficient batches of this color as may be necessary for Texas and Florida oranges. But the court provided that nothing in its judgment should restrict the Secretary from making further investigations and conducting hearings to determine whether Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless. Under

Judicial review in the Court of Appeals for the

the judgment, Red 32 will have to be retained on the approved list and certified by the Secretary as harmless for coloring oranges "until there is evidence that in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption."

5. Before the administrative process had been completed, steps were taken in the Congress to enact legislation to keep Red 32 on the approved list for coloring oranges. After the tentative order issued (R. 52-54), a bill was introduced into the 84th Congress, H. R. 7732, to require the Secretary to continue the certification of Red 32 for coloring oranges until a color that is "more acceptable" (less toxic) should be "listed and made available for use." Hearings were held before the House Committee on Interstate and Foreign Commerce on February 10, 1956, a few days after the present cases were filed in the Court of Appeals for the Fifth Circuit. The Department of Health, Education and Welfare opposed the bill. It proposed a temporary compromise to continue Red 32 on the list for coloring certain oranges for a period of not to exceed 3 years. This, it explained, was to allow time "for the development of a color that is not toxic," "for further exploration of the toxicity of FD&C Red 32," and "for further congressional consideration if a new color should not be found, and if it should be necessary to amend the law to authorize the Department to prescribe a tolerance for Red 32 on oranges and impose other conditions to safeguard public health." In doing this, the Department explained that it had no positive proof that this temporary use would



involve a likelihood of injury, but neither was there evidence available to establish that this use was wholly safe. On the other hand, the Department said that it could not agree to H. R. 7732, which would require the indefinite listing of Red 32 for oranges "before its safety for the purpose has been finally established" (Hearings, House Committee on Interstate and Foreign Commerce on H. R. 7732, 84th Cong., 2d Sess., pp. 2-3).

Both the House and Senate Committees adopted the Department's recommendations, and both made it clear that this temporary legislation was not intended to affect the outcome of the judicial review proceedings then under way in New York, Chicago, and New Orleans. H. Rep. 1982, 84th Cong., 2d Sess., p. 3, and S. Rep. 2391, 84th Cong., 2d Sess., pp. 2-3.

The result of this Congressional consideration was Public Law 672, 84th Cong., 2d Sess., enacted July 9, 1956, under which the Florida and Texas orange growers were exempted from the prohibitions against Red 32 (now External D and C Red No. 14) until March 1, 1959.\*

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\* Public Law 672 reads as follows:

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That paragraph (c) of section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting immediately before the period at the end thereof a colon and the following: "*Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have*



## REASONS FOR GRANTING THE WRIT

Section 406 (b) of the Federal Food, Drug, and Cosmetic Act directs the Secretary of Health, Education, and Welfare to promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food. Under that provision, the Secretary has, in the order under review, barred Red 32 and two orange colors. The order flatly prevents use of these colors, for Section 402 (c) defines a food as adulterated if it "bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406". Until March 1, 1959, there is the temporary statutory exception from Section 402 (c)—noted in the Statement, *supra*, p. 11—granted by P. L. 672 to Red 32 used for coloring oranges. But in invalidating the Secretary's order, the court below has, in effect, read into Section 402 (c) a permanent exception which not only will apply to coloring for oranges beyond March 1959, but which will permit possible exceptions in other fields as well. The court has held that there must be inserted into Sections 402 (c) and 406 (b) (dealing specifically with coal-tar colors) the provisions of Section 406 (a) which declares that the Secretary may permit the adding of a poisonous or

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been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406".

deleterious substance to food "where such substance is required in the production thereof or cannot be avoided by good manufacturing practice," under regulations limiting the quantity which the Secretary finds necessary for the protection of public health. Then the court goes still further to construe "required in the production thereof," as used in Section 406 (a), as meaning required for marketing by a "substantial segment" of the orange-producing industry. Finally, the court decides (Appendix, *infra*, p. 46) that the use of coal-tar coloring for oranges should be continued, irrespective of the date fixed by Congress, and regardless of any proof by respondents that a safe tolerance can be fixed, until the Secretary is prepared to show that "in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption."

We believe that this erroneous decision warrants review and correction by this Court. Its reasoning and result conflict with that of the Second Circuit in *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 236 F. 2d 866. It effectively defeats the object of Congress—in passing P. L. 672, the temporary legislation—of stimulating the color industry to develop new and safer coloring. And the decision sets up requirements for the certification of coal-tar colors which have significant and immediate impact, not only beyond the period fixed by Congress for oranges, but for other coal-tar colors used on other foods, *e. g.*, yellow colors used principally in margarine. For these reasons it is important that the ruling below be reviewed at this time.

A. There is a basic conflict between the decision below and that of the Second Circuit in the *Certified Color* case. It is true, as the majority opinion below points out, that *Certified Color* involved the question of the use of Red 32 generally, whereas this holding concerns only Red 32 as applied to coloring for oranges. But the fact is that the Second Circuit's judgment precludes certification of Red 32 to manufacturers while the present judgment requires the Secretary to issue certificates of harmlessness of Red 32 to the same manufacturers so long as they say they intend to sell the color to Texas and Florida orange growers.

There is also a direct conflict in reasoning. The Second Circuit held that, even if the Secretary had power to fix tolerances for coal-tar colors (a question it did not decide), the court could not, on the record before it, require the Secretary to do so. It pointed out that there was nothing in the record to indicate how much of the coal-tar colors a human being could ingest over a period of years without harmful effects, and that it might not be possible to demonstrate the precise cumulative effect, over 20 to 30 years of consumption, of specified amounts of color. On the other hand, the court below, on the same record, made a determination that coloring for oranges is safe, merely on the basis of the Secretary's statement that coloring for oranges has not been proved to be harmful, and without considering what effect there might be if other industries could show

a similar need for harmful coloring. In contrast to the Second Circuit, the ruling below does require the Secretary to establish tolerances unless he affirmatively proves that the court's assumption as to the safety of Red 32 is wrong. In short, the court below has given its stamp of approval to an acknowledged poison and cast the burden on the Secretary to show that the coloring is not safe for oranges. The Second Circuit has held that the Secretary has no such burden.

B. There is a present need for resolution of this conflict of circuits, even though the temporary statute suspends the operation of the Secretary's order, as to Red 32 for oranges, for another year. Congress intended by P. L. 672 to press the color industry and the orange growers into prompt development of a harmless color or at least into scientific research which might provide a sound factual basis for a safe tolerance for Red 32 on oranges. See the terms of P. L. 672, fn. 3, *supra*, pp. 11-12.\* The Second Circuit

\*The temporary legislation did not revoke the Secretary's order nor modify its terms. What it did was to excuse the Texas and Florida orange growers from adulterations that would otherwise arise prior to March 1, 1959, from the use of Red 32 (now External D&C Red No. 14). Though the order remains in effect under the statute, insofar as it removed Red 32 from the "harmless" list a statutory exception to the adulteration defined in Section 402 (c)—the use of uncertified coal-tar colors on foods—was made so that it may not be applied prior to March 1, 1959, against the Texas and Florida growers who use Red 32 under the conditions specified in the exception. Fourteen months from now the exception expires by its own terms, and any oranges colored with Red 32 would thereupon be deemed adulterated.

has also left the burden where it belongs, on the industry either to prove that the color is safe or to discover a safe new product.

The decision below means, however, that the industry and the growers can rest on the Fifth Circuit's judgment and do nothing—that it is the Department which must develop the facts to show a positive danger to health before it can preclude the use of a color it has proved to be generally poisonous. There is now no reason for the industry to institute studies or to take action. On the other hand, the scientific evidence to support the course of action required of the Secretary by the court below does not now exist, and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced. If the Secretary really does have the burden which the decision below casts upon him, he should know that now. If, as we think, the burden is properly on the industry, the decision below, under which the industry need do nothing, should not be allowed to stand.

Moreover, the decision below has a direct and immediate impact upon other colors and other proceedings. For example, on May 4, 1957, the Department published an order removing certain yellow colors, used principally in margarine, from the list of colors available for unrestricted use in food, drugs, and cosmetics. The reasoning applied by the court below to Red 32 may well be urged in relation to oleomargarine. The Secretary should know whether, in the promulgation of this order, he must be guided by the decision of the Second Circuit or by the ruling



of the court below. Coloring is probably as important a factor in the marketing of margarine as it is in the distribution of oranges.\* The Fifth Circuit's decision thus has an immediate practical effect, both with respect to coloring for oranges and in its wider implications for the Secretary's color proceedings in general.

C. Nor have the issues become moot in the technical sense because the temporary legislation postpones the effectiveness of the order with respect to oranges. Review of the Secretary's regulations is authorized by the Federal Food, Drug, and Cosmetic Act, and must be sought within 90 days after the final rules are announced. Any person who will be adversely affected if the order is placed in effect is given standing to challenge the rules. Since this involves judicial review of administrative rule-making, it is always the future effect of the regulations rather than their past application which makes the case justiciable. In *Federal Security Administrator v. Quaker Oats Company*, 318 U. S. 218, the regulations were issued May 26, 1941, to be effective January 1, 1942. Review proceedings were begun on August 22, 1941.\*

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\* In addition to the basic holding below that the Secretary must establish tolerances, there is the additional ruling that he must consider sales appeal as a factor in determining whether a toxic color is "required in the production" of food. Both questions would be important in passing (under the rules laid down below) on the suitability of certain yellow colorings for margarine.

\* The requirement that riboflavin be an ingredient of enriched farina was not to become effective until April 1943, because that vitamin was in short supply. 318 U. S. 223, fn. 3.

It is not at all unusual for an executive agency to place an effective date on its rules which will allow the affected industry time to adjust to the new requirements.' But a postponed effective date does not destroy the right to judicial review. Review can be obtained only within 90 days after promulgation of the rules, though they may not become effective by their own terms for a year or more. In this case, the fact that Congress, rather than the executive agency, gave the citrus growers additional time to adjust to the new rules does not preclude or frustrate the statutorily-permitted judicial review.

In *Reade v. Ewing*, 205 F. 2d 630, the Court of Appeals for the Second Circuit held that a consumer had standing to obtain review when he alleged that the Secretary had erroneously permitted synthetic vitamin A in the standard for oleomargarine, and that the petitioner's health might be adversely affected if the ingredient was, as he alleged it to be, of uncertain safety. The consumer was characterized as a private attorney general to bring suit to restrain wrongdoing public officials. His interest was much more remote than that of the Texas and Florida orange growers, for so long as the Secretary's order stands they must immediately take action to develop a harmless substitute color or to study the toxic potential of Red 32, and the oranges containing it, to provide the evidence on which a safe tolerance

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' Only recently the Department issued new rules respecting the label statements that must be made concerning the niacin and riboflavin content of foods for special dietary use. The effective date of the rules was set for July 1, 1958, to permit the necessary revision of existing labels. 22 F. R. 4910.

may be established. Since such studies require at least two years, it is obvious that the order immediately affects them even though it may not be applied to condemn their oranges before March 1, 1959.\*

## II

Not only are the rulings of the court below of decided current and future importance; they are also demonstrably incorrect.

A. The court first erred in holding that the provisions of Section 406 (a) (enabling the Secretary to fix tolerances for deleterious substances required in production) operate as an exception to Section 402 (c), providing that a food is adulterated if it bears a coal-tar color other than one which has been certified as harmless under Section 406 (b). Coal tar colors have always been recognized as having potentialities of danger. See Calvery, *Coal-Tar Colors*, *The American Journal of Pharmacy*, Vol. 114, No. 9; Statement of Walter G. Campbell, on S. 1944, 73d Cong., 2d Sess., Dunn, *Legislative History, Federal Food, Drug, and Cosmetic Act* (1938), p. 1066. In the very same Section 406 in which Congress provided in subdivision (a) for tolerances when required, it enacted subdivision (b) providing for the certification only of harmless coal-tar colors. This special singling out of coal-tar colors shows that Congress considered them a special problem. In all the Congressional dis-

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\* This Court's decisions in *Columbia Broadcasting System v. United States*, 316 U. S. 407; *United States v. Storer Broadcasting Co.*, 351 U. S. 192, and *Pierce v. Society of Sisters*, 268 U. S. 510, also support our view that the case is still ripe for consideration.

cussion of Section 406, paragraphs (a) and (b) were discussed separately and there was no suggestion anywhere that a tolerance for a poisonous coal-tar color could or should be established under paragraph (b).

The legislative history of 406 (b) likewise shows that Congress intended the Secretary to list "those colors which were demonstrated to be without adverse physiological action, and which from a technical standpoint were suitable for use as food colors." S. Rep. 361, 74th Cong., 1st Sess., pp. 6-8 (1935); Dunn, *Legislative History, Federal Food, Drug, and Cosmetic Act*, (1938), p. 243. Congress intended to correct a weakness of the original 1906 Pure Food and Drugs law under which "[n]o action [could] be taken unless it [could] be proved that colors or their impurities are poisonous *and that they are present in such quantities as may be harmful to health*" (emphasis added). Senator Copeland's memorandum on S. 1944, 73d Cong., Dunn, *op. cit.*, pp. 30-31. The new law was designed to prevent the use of poisonous coal-tar colors without the necessity of proof that the poison was "present in such quantities" in a particular food to render that food "injurious to health." *Wood Manufacturing Co. v. United States*, 286 Fed. 84 (C. A. 7), is the case Congress intended to overturn.

The purpose of Section 406 (b) was to require the Department to list and certify only innocuous coal-tar colors, which could then be used by all food, drug, and cosmetic manufacturers, without restraint as to quantity or commodity, in order to achieve any desired tinctorial hue in or on any number of commodities. There was no idea of authorizing the use of

poisonous colors on a single food, even within the limits of stringent tolerances; the danger of cumulation of the poison, over a period of years, was believed too great to permit such necessarily-inaccurate tolerances. And the whole question of safe tolerances becomes much different if more than one product is involved. Assuming that the amount of coloring used for oranges alone would be safe, and in itself the amount of coloring used for margarine would be safe, there would still remain the question of whether the amount of coloring used in both margarine and oranges would be harmless. And since there may be other industries which would make out a similar case for toxic coloring, the question of safe tolerances becomes even more complicated and hazardous to assay.

B. Even assuming that coal-tar colors could come within the scope of the "tolerances" provision of Section 406 (a), the Fifth Circuit has misinterpreted that section in holding that "required in the production" means "required in the production *for market*" by a particular industry (Appendix *infra*, pp. 41-43, emphasis added).

By Section 406 (a), Congress established a strict rule of exclusion against all poisonous and deleterious substances which might be added to our foods. This was without regard to whether the added substances might or might not render the treated food injurious to health. It was enough that the added substance itself was a poisonous or deleterious one. A single exception was made. When the added substance was required in the production of food or could not be avoided by good manufacturing practice, the Secretary was authorized to establish a tolerance for it,



taking into account the extent to which the added substance was required or was unavoidable, the amount of the poison that might be safely tolerated, the extent of requirement or unavoidability of the poison on other foods, and the other ways in which the consumer might be affected by the same or other poisonous or deleterious substances.

This was a new legislative approach to added poisons. Under the Pure Food and Drugs Act of 1906, Section 7, 34 Stat. 768, 770, food was declared adulterated if it contained and added poisonous or deleterious ingredient "which may render such article injurious to health." This Court, in *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399, 409-411, held that under the 1906 language a food was adulterated if it contained any added poisonous or deleterious ingredient which may possibly injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." If the added substance in the food could not "by any possibility" injure the health of any consumer, the small addition of poisonous or deleterious ingredients was not condemned. As strong as this prohibition was, it did not go far enough. Each food had to be considered alone, and there was no adulteration unless the particular food contained enough poison so that that food "may" be injurious to health. Small amounts of the same poison in a variety of common foods in the diet were beyond effective control.

The new provision in Section 406 (a) of the Federal Food, Drug, and Cosmetic Act was designed to arm the Department with power to establish tolerances for the entire variety of foods in which a

common poison or related poisons were required or were unavoidable, and thereby to limit the total intake of each such poison to a safe level. See testimony of Walter G. Campbell, Chief, Food and Drug Administration, before the House Committee on Interstate and Foreign Commerce, on S. 5, 74th Cong., Dunn, *op. cit.*, pp. 1250-1251; H. R. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, p. 820.

Considering the very narrow scope of this exception created by Congress, it is inconsistent with its purpose to construe "required in the production" to cover post-harvest treatment of fruit, after it has been produced, for the sole purpose of making it look more attractive and therefore more readily salable. This interpretation of Section 406 (a) as justifying use of poisons when required for *marketability* opens up all sorts of possibilities beyond coloring as such. If marketability rather than actual production is to be the test of necessity, it is evident that the amount of poison in the American diet can be greatly increased.

C. Even assuming the correctness of the statutory interpretations by the court below, it erred in itself making the requisite finding that coloring of oranges was required for production (including marketing) and casting the burden on the Secretary to show that safe tolerances cannot be established. As we have noted, tolerances safe for oranges alone might not be safe if, under the interpretation of the court below, other products can also show that they should be allowed to use coal-tar colors because required in their "production" or marketing. The fact that Congress created (in P. L. 672) a deferment for one particular

product, on a finding that the amount of coloring used in that product for a short period would not endanger public health, does not justify a court in making the judgment on its own, on a theory of the statute which would also apply to other products and for an indefinite period. And certainly the burden of showing danger from an admitted poison should not rest on the Secretary. Even on the court's own view, it should have remanded the case for further proceedings without setting aside the order.

#### CONCLUSION

For the foregoing reasons, we believe that this petition for a writ of certiorari should be granted and the case determined on its merits at this time. However, should the Court be of the view that no decision should be reached on the important questions discussed above until after March 1, 1959, when P. L. 672 expires, we urge that certiorari be granted, the judgment of the Court of Appeals vacated, and the case returned to it for disposition after the temporary legislation ends.

Respectfully submitted,

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*Department of Health, Education*  
*and Welfare.*

JANUARY 1958.

**APPENDIX**

**In the United States Court of Appeals  
for the Fifth Circuit**

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**No. 15934**

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**FLORIDA CITRUS EXCHANGE, ET AL., APPELLANTS**

**v.**

**M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE, APPELLEE**

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**No. 15948**

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**FRANK R. SCHELL, APPELLANT**

**v.**

**M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE, APPELLEE**

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**ON PETITIONS FOR REVIEW OF AN ORDER OF THE SECRETARY  
OF HEALTH, EDUCATION AND WELFARE**

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**(July 12, 1957)**

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**Before HUTCHESON, Chief Judge, and JONES and  
BROWN, Circuit Judges.**

**JONES, Circuit Judge:** In the nineteen-thirties growers and packers of oranges in Florida and Texas began the practice of adding color to the rind of oranges. Early oranges, maturing during warm



weather, will ripen to full maturity with the skin still green in color. Oranges maturing in the late winter or spring may fully ripen and undergo a "regreening" of the rind. The orange-purchasing public requires an orange-colored orange and will not accept those with green rinds. Representatives of a substantial number of those engaged in the growing and marketing of citrus fruits in the two states assert that severe economic reverses would result from a prohibition of adding color to the fruit; indeed it has been asserted that the future of the orange industry of these states is dependent upon the continued coloring of its product.

In 1938 the Congress enacted the present Federal Food, Drug and Cosmetic Act. 52 Stat. 1040; 21 U. S. C. A. §§ 301-392. The adulteration of food in interstate commerce and the introduction of adulterated food into interstate commerce were prohibited. 21 U. S. C. A. § 331. Congressional standards for determining when food would be deemed adulterated were set up.<sup>1</sup> Provisions for tolerances of

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<sup>1</sup> "A food shall be deemed to be adulterated—

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is

poisonous and deleterious substances were included."

composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 406; *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

" 52 Stat. 1046, § 402, 21 U. S. C. A. § 342.

"(a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is re-

The Secretary of Agriculture, to whom the administration of the Act was originally committed, issued regulations on May 4, 1939, effective May 9, 1939, governing the listing of coal-tar colors.<sup>3</sup> Among those eligible for certification were listed FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.<sup>4</sup> In 1954 the Secretary of Health, Education and Welfare, succeeded to the administration of the Act in the place originally held by the Secretary of Agriculture.<sup>5</sup> The Secretary reached the conclusion that the three colors are not "harmless" as that word is used in Section 406 (b) of the Act. 21 U. S. C. A. § 346 (b). An order promulgating a further regulation<sup>6</sup> was issued by which the three colors were deleted from the list approved for certification for use in foods and in drugs to be taken internally. By Section 701 (f) of the Act,<sup>7</sup> any person who will be adversely affected by an order of the Secretary may file a petition for review with the court of appeals for the circuit wherein such person resides. Petitions for review were filed in three circuits. In the Seventh Circuit the proceeding for review was dismissed. In the Sec-

quired or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

"(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." 52 Stat. 1049, § 406, 21 U. S. C. A., § 346.

<sup>3</sup> 4 F. R. 1935, 1 C. F. R. 1939 Supp. 1214 et seq.

<sup>4</sup> 4 F. R. 3936, 1 C. F. R. 1939 Supp. 1214, 1218.

<sup>5</sup> Reorganization Plan No. 1 of 1953, 67 Stat. 631, 18 F. R. 2053; 67 Stat. 18, 5 U. S. C. A. § 623.

<sup>6</sup> 20 F. R. 8492.

<sup>7</sup> 21 U. S. C. A. § 371 (f).

ond Circuit, by a decision which we shall hereafter discuss, the Secretary's order was affirmed. *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 2 Cir. 1956, 236 F. 2d 866. Two petitions for review have been filed in this Circuit, one by Florida Citrus Exchange and others, orange growers and packers of Florida and Texas, and the other by Frank R. Schell, the holder of patents on the process for the coloring of citrus fruits with Orange 2 and Red 32. The two proceedings for review in this Court have been consolidated. Red 32 is the only one of the three colors with which we are concerned in this proceeding.

The three colors were on the original list, prepared in 1939, of coal-tar colors available for certification. Some of the coal-tar colors on the list became suspect as toxic and possibly carcinogenic. This prompted further investigation which culminated in the hearings which formed the bases of the order which we here review. At the hearing evidence was introduced that rats did not survive a diet of 1000 parts per million of Red 32. A dog fed 100 parts per million of Red 32 sickened and ultimately died. This was the lowest percentage tested of Red 32. Evidence was introduced at the hearing which showed that Red 32, when used for coloring oranges penetrated the skin for a depth of about 1/1000 of an inch; that peel of the colored orange had from 17.63 to 34.26 parts per million of color; candied orange peel had 7.4 parts per million of color; orange marmalade analyzed 1.8 parts per million of color; and the squeezed juice of colored oranges had a color content range of from 4/100 of one part per million to 7/100 of one part per million. A spokesman for the entire coal-tar color industry stated that the



sale of Red 32 had been discontinued for any purpose except the coloring of oranges. The principal witness for the Secretary was Dr. Vos, Assistant Chief of the Division of Pharmacology of the Food and Drug Administration. He reviewed the tests made upon animals. He testified that on the basis of the experiments and his education and experience he was of the opinion that Red 32 was not a "harmless coal-tar color". On cross-examination he stated that he used the word "harmless" in the absolute sense that the color was capable of producing harm. This was developed by his saying that bad results might follow the taking of two or three ounces of salt but, salt being essential, it would not be regarded as harmful. He had no evidence as to whether the color would produce harmful effects at ordinary levels of use, although he gave an affirmative answer to the question "Aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended?"

The order of the Secretary which we here review made findings of fact based upon the evidence of the tests of which Dr. Vos testified. At the conclusion of nine paragraphs of specific findings as to the effects of the various quantities of the colors given to animals with mention of one episode of illness resulting to man from eating popcorn colored with Orange 1 where the percentage level did not appear, the Secretary stated:

"There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs, and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be

small to the point of insignificance. But those contentions leave aside the occurrence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of food, drugs, and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges.”

By the order it was determined that Red 32 and the other two suspect coal-tar colors were not harmless and suitable for use in food, drugs and cosmetics and these colors were deleted from the approved list. The legal theory upon which the order was based is found in paragraph 2 of the Secretary's conclusions where it was held:

“Sections 406 (b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 346 (b), 354, and 364) provide for the listing of coal-tar colors that are harmless and suitable for use in food, drugs, and cosmetics. The act does not provide any method for listing toxic colors for specific food, drug, or cosmetic uses so as to limit their total use to small enough amounts that the toxicity might be disregarded. Under the statute a toxic color cannot be classified as a harmless color.”

The primary attack of the petitioners is upon the correctness of the principle as stated in the foregoing quotation.

When the order of the Secretary was entered an effort was made to procure an amendment to the Act to require the Secretary to permit Red 32 to be used in coloring oranges until a more acceptable color should be made available. The amendment as orig-

inally offered was opposed by the Department of Health, Education and Welfare. The measure, as finally agreed upon by its proponents and representatives of the Department, amended Section 402 (c) of the Act by adding thereto the following:

“Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as ‘packing house elimination’), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External O&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406”.  
70 Stat. 512; 21 U. S. C. A. § 342 (c).

While this amendment was pending before the House of Representatives where it had its origin,\* a committee hearing was held. Before the committee was a letter from the Secretary of Health, Education and Welfare where it was stated that the evidence so far available does not establish what the lowest safe dosage of Red 32 would be to test animals, neither does it establish a likelihood of injury to man from the use of the color on the exterior of oranges at the levels of use involved. The studies, said the Secretary, were not designed to determine whether a safe tolerance could be established for a single food, such

\* H. R. 7732.

as oranges, so that the amounts that might be consumed as color on the exterior surface of oranges would pose no undue risk.<sup>9</sup> The Commissioner of Food and Drugs appeared and gave a statement at the hearing similar to and in some respects amplifying those contained in the Secretary's letter. He reiterated that the tests made were not designed to learn the effect upon human beings of the minute quantities of the color that might be ingested by its use as an orange coloring. He stated that although the color had been used on oranges since in the early 1930's, no evidence has been found that injury has resulted from the consumption of oranges so colored. This use, said the Commissioner, presented a strong equity for conducting tests. He stated, as did the Secretary, the view of the department that if the color was "harmful" its use must be prohibited and that no tolerances could be fixed.<sup>10</sup> Among the purposes of the amendment, as explained in the report of the Committee of the House of Representatives, was the allowing of time for further exploration of the toxicity of Red 32. In the report it was stated that the practice of coloring the skins of oranges has become an economic necessity for a major segment of the orange industry.<sup>11</sup> In the report of the Senate Committee on Labor and Public Welfare, to whom the bill was referred, the same conclusions were reached.<sup>12</sup> On this factual situation and background we review the order of the Secretary.

<sup>9</sup> Hearing before a Subcommittee of the Committee on Interstate and Foreign Commerce House of Representatives, 84th Cong., 2d Sess. on H. R. 7732, pp. 2 and 3.

<sup>10</sup> Hearing, *supra*, pp. 17 and 18.

<sup>11</sup> H. R. Rep. No. 1982, 84th Cong. 2d Sess.

<sup>12</sup> S. Rep. No. 2391, 84th Cong. 2d Sess.



The petitioners list twelve specifications of error upon which they ground their attack upon the Secretary's order. The basic and underlying contention of the petitioners is that the Secretary has erred in construing "harmless", as used in Section 406 (b) of the Act, in an absolute rather than in a relative sense. If the position of the Secretary is correct, he has no choice but to refuse to permit a coal-tar color to be used in food in minute, safe and harmless quantities if, when used in much larger quantities it would or might be injurious or dangerous to health. If the position of the Secretary is correct he has no power to permit a particular coal-tar color to be used for a specific and restricted purpose even though, when so used, it would not be injurious or dangerous to health.

The Secretary has urged that the questions presented for our review are the identical questions which were decided by the Second Circuit in *The Certified Color Industry Committee v. The Secretary of Health, Education and Welfare*, *supra*, and that we should follow that decision unless we are convinced it was clearly wrong. Where an identical issue is presented and no different principle is involved, the decision of another court of appeals is entitled to great weight and affords persuasive argument." Although the appeal in the *Certified Color Industry* case was from the same order and was upon the same record as the case before us, the identical issue is not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all inclusive. The differ-

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<sup>11</sup> *Sokol Brothers Furniture Co. v. Commissioner of Internal Revenue*, 5 Cir. 1950, 185 F. 2d 222, reh. den. 185 F. 2d 677, cert. den. 340 U. S. 952, 71 S. Ct. 571, 95 L. Ed. 686.

ence was recognized by the Court of Appeals for the Second Circuit. In its opinion it is said:

"Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects." 236 F. 2d 871.

The problem we consider is not that which the Second Circuit had and the decision there is, as we hope to show, not in conflict with what we decide here.

In a brief filed with us by amicus curiae, he quotes from a letter to him from the Food and Drug Administration where it was said:

"Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color is inherently deceptive and is contrary to the interests of both consumers and producers."

This letter is not in the record and would not be the subject of comment by us but for a suggestion that it evidences a hostile and prejudiced attitude of the Food and Drug Administration. We think the record shows the contrary to be the case. It is shown that all oranges to which color is added are so marked and that immature fruit is not colored. The record reflects a departmental attitude of fairness and objectivity, and discloses that the ill-advised statement of the writer of the letter does not express the view of the Secretary or of the department.

It has been contended that the officers charged with the administration of the Act had, from the time the

Act was passed until the time of the investigation which culminated in the hearings and in the order we here review, construed the Act as permitting, if not requiring, the fixing of tolerance for harmless uses of Red 32. Such administrative construction should be persuasive, so we are told, if not binding as an administrative construction of an ambiguous provision. The Secretary, on the other hand, asserts that the administrative interpretation has not altered, and that the change of position resulted from the different findings of fact required by the recent investigations and experiments. We need not pursue this inquiry. An administrative construction which is clearly erroneous is not binding on the administrative agency nor is it persuasive in judicial proceedings," and this should be particularly true where the purpose of the Act is to protect the health of the public." The doctrine of giving weight to an administrative construction of a statute does not apply to an administrative determination of the administrator's statutory powers." This, in essence, is one of the questions before us.

The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as FD&C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges; and if so required or permitted, and if it be determined that

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<sup>82</sup> 82 C. J. S. 771, Statutes § 359 b.

<sup>83</sup> The purposes of the Act are discussed *infra*.

<sup>84</sup> *Stark v. Brannan*, D. C. D. C. 1949, 82 F. Supp. 614, aff. 87 U. S. App. D. C. 388, 185 F. 2d 871, aff. 342 U. S. 451, 72 S. Ct. 433, 96 L. Ed. 497.

there is such minimum, should the Secretary list and certify such color for such use. In the construction of statutes courts will look to the entire act and to its objects and policy.<sup>17</sup> Results which are incongruous<sup>18</sup> or absurd<sup>19</sup> are to be avoided. Where a particular construction of a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute.<sup>20</sup> In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined.<sup>21</sup> These rules are the primary guides to our solution of the problem before us.

In the leading and often cited Lexington Mill case<sup>22</sup> the Supreme Court declares the purpose of the Act, saying:

"The statute upon its face shows, that the primary purpose of Congress was to prevent injury to the public health by the sale and transportation in interstate commerce of misbranded and adulterated foods. \* \* \* As against adulteration, the statute was intended to protect the

<sup>17</sup> *Mastro Plastics Corporation v. National Labor Relations Board*, 350 U. S. 270, 76 S. Ct. 349, 100 L. Ed. 309, *National Labor Relations Board v. Lion Oil Co., et al*, 352 U. S. 282, 77 S. Ct. ...., 1 L. Ed. 2d 331; *United States v. Witkovich*, 353 U. S. 194, 77 S. Ct. ...., 1 L. Ed. 2d 765.

<sup>18</sup> *National Labor Relations Board v. Lion Oil Co., et al*, *supra*.

<sup>19</sup> *United States v. American Trucking Associations, Inc.*, 310 U. S. 534, 60 S. Ct. 1059, 84 L. Ed. 1345; *Fulford v. Forman*, 5 Cir. 1957, .... F. 2d .....

<sup>20</sup> *Knowlton v. Moore*, 178 U. S. 41, 20 S. Ct. 747, 44 L. Ed. 969.

<sup>21</sup> *United States v. Freeman*, 44 U. S. (3 How.) 556, 11 L. Ed. 724.

<sup>22</sup> *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed. 658.



public health from possible injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers." 332 U. S. 409.

The purpose to protect the public health is an important aim of the statute,<sup>22</sup> and touches phases of the lives and health of people which are largely beyond self-protection.<sup>23</sup>

We are here reviewing the order of the Secretary only with respect to the coal-tar color FD&C Red No. 32 as used in the coloring of the skins of oranges. If there be other like situations, then of course that which we hold will be applicable to them. We are not confronted with the broad questions which were before the Second Circuit in the *Certified Color Industry* case, *supra*.

In some of the cases<sup>24</sup> the de minimis doctrine has been recognized as applicable or has been applied in adulterated food cases. The contentions of the petitioners suggest that they regard the doctrine applicable here. Neither the Secretary's findings nor the evidence on which they were based calls for any consideration of the doctrine upon the record before us.

<sup>22</sup> *United States v. Coca-Cola Co.*, 241 U. S. 265, 36 S. Ct. 573, 60 L. Ed. 995.

<sup>23</sup> *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134, 88 L. Ed. 48, reh. den. 320 U. S. 815, 64 S. Ct. 367, 88 L. Ed. 492; *62 Cases of Jam v. United States*, 340 U. S. 593, 71 S. Ct. 515, 93 L. Ed. 566.

<sup>24</sup> *United States v. 449 Cases*, 2 Cir. 1954, 212 F. 2d 567, 45 A. L. R. 2d 846; *338 Cartons v. United States*, 4 Cir. 1947, 165 F. 2d 728; *A. O. Andersen & Co. v. United States*, 9 Cir. 1922, 284 F. 542; *United States v. 298 Cases*, D. C. Ore. 1949, 88 F. Supp. 450; *United States v. 184 Barrels*, D. C. E. D. Wis. 1943, 53 F. Supp. 652; *United States v. 133 Cases*, D. C. E. D. Pa. 1938, 22 F. Supp. 515.

The words "harm", "harmful", and "harmless" are terms of relation. In this sense they resemble "wrong" and "wrongful".<sup>22</sup> Red 32 is harmless, i. e. not harmful, to all persons under the protection of the Act while it remains in the vat or the vial. An injury must occur before harm results. The color Red 32 becomes harmful, i. e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such small quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he would be had he consumed none of it.

In *United States v. Lexington Mill & Elevator Co.*, *supra*, the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it "contain any added poisonous or other added deleterious ingredient which may render such article injurious to health". It was contended there, as it is contended here, that it is the character—not the quantity—of the added substance which is to determine the case. This contention was rejected. The Court said:

"If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act." 232 U. S. 411.

<sup>22</sup> Cf. *Palsgraf v. Long Island Railroad Co.*, 248 N. Y. 339, 162 N. E. 99, 59 A. L. R. 1253.

As in the *Lexington Mill* case, it was held in the Seventh Circuit that "injurious" is a relative rather than an absolute term. *W. B. Wood Mfg. Co. v. United States*, 7 Cir. 1923, 286 F. 84. We think "harmless" is also to be so construed.

The Secretary would concede, apparently, the possibility that a person might consume Red 32 in such small quantities that no hazard to health would result. His guarded statement is that "the evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved."<sup>27</sup> The Commissioner of Food and Drugs has admitted that there was no evidence of injury to consumers of colored oranges.<sup>28</sup> The Secretary has made no effort to ascertain whether or not there is, in fact, any likelihood of injury to the health of persons who consume oranges colored with Red 32. Taking the position that no quantitative test is authorized, the Secretary disclaims any power to fix a tolerance for the use of Red 32 in the coloring of oranges or for any other particular use. Under this theory it would make no difference whether or not there was a minimum quantity of Red 32 which would not be injurious. *Malum in uno, malum in omnibus*, is the departmental canon of construction.

Unless the quantities of Red 32 used in the coloring of oranges are dangerous to public health, the objects and purposes of the Act will not be promoted by a construction which prohibits that use in such quantities. The statute which we construe provides for the fixing of tolerances for added poisonous and deleterious

<sup>27</sup> Hearing, *supra*, p. 3.

<sup>28</sup> Hearing, *supra*, p. 18.

substances required in the production of food<sup>29</sup> and, by a 1954 amendment,<sup>30</sup> for the fixing of tolerances for poisonous pesticides on raw agricultural commodities. We cannot see how the objects and purposes of the statute would be furthered by a construction which permits safe, i. e. harmless, quantities of poisons other than coal-tar colors to be added to food where required in its production, and which permits safe tolerances of poisons for pesticides, but prohibits the use of a coal-tar color in the most minute and harmless quantity because it is harmful and injurious in large quantities. Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and injustice. There is, we think, a more reasonable interpretation in the Act.

The Secretary found that Red 32 is toxic; in other words that it is poisonous. The evidence justified the finding. If the Secretary is correct in his construction of "harmless", Section 402 (a) of the Act is inapplicable to coal-tar colors. If his construction is erroneous, Section 402 (a) would apply. If Section 402 (a) applies, the colored oranges would be "adulterated" only if the added poisonous substance was unsafe within Section 406 (a). Under this section poisonous substances are permitted to be added to food if it "is required in the production thereof" within such limits as to quantity or extent as the Secretary finds necessary for the protection of public health. The Committees of the Senate and the House of Representatives each found that the practice of

<sup>29</sup> 21 U. S. C. A. § 346 (a).

<sup>30</sup> 68 Stat. 511, 21 U. S. C. A. § 346 a.



coloring oranges has become an economic necessity for a major segment of the orange industry since a high percentage of the oranges grown in Florida and Texas would meet with strong consumer resistance if not colored.<sup>21</sup> It is as important for a food to be marketable as for it to be palatable and, if the findings of the Committees be correct, then the addition of color is "required in production", as that phrase is used in the Act. Section 402 (a) and Section 402 (c) are not mutually exclusive. A coal-tar color may not be added unless from a certified batch. By Section 406 (b) only those coal-tar colors may be certified which the Secretary has listed as harmless. The Secretary and his colleagues in the Department did not oppose the enactment of the 1956 amendment to Section 402 (c). A reason given was that during the period of the moratorium a "non-toxic color" might be developed. It is the contention of the petitioners that no colors other than Red 32 and the others banned by the Secretary's order are effective. If another color be found which is not a coal-tar color but is as much or more toxic, then we see no reason to doubt that the Secretary would be required to deal with it under Section 406 (a) and to provide tolerances for its use in the event it could be used in any limited quantity without being injurious to the public health. The Secretary, in his order, has stated that "the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics". It is not apparent that this is a problem with respect to other toxic substances which are added to foods under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color. We see no reason for supposing that Congress intended to permit the use of toxic sub-

<sup>21</sup> S. Rep. No. 2391, *supra*; H. R. Rep. No. 1982, *supra*.

stances, including toxic colors other than coal-tar products, in safe and harmless quantities and to prohibit the use of toxic coal-tar colors in safe and harmless quantities. We do not ascribe such an intention to Congress. Another reason given by the Secretary for not opposing the 1956 amendment was that the moratorium for Red 32 would permit further exploration of its toxicity. It is the view of the Secretary that if it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required. With this conclusion we do not agree.

We construe the Act as requiring the Secretary, under Section 406 (a), to determine whether the use of the color Red 32 is required in the production for market of oranges grown by a substantial segment of the orange producing industry; and if he finds that such use is so required, then to determine the quantity, if any, that can be tolerated as safe, and by regulation to limit the quantity to such extent as he finds necessary for the protection of public health. With "harmless", as used in Section 406 (b), construed as a relative rather than an absolute term, regulations promulgated by the Secretary under that section as well as under Section 406 (a) could be issued if the prerequisite findings as to the necessity for using color had been made and the tolerance limits had been fixed.

In the order of the Secretary it is stated that there is no "authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges". Although there may be no express statutory provision authorizing the limiting of the use of a color to a single food, it is not prohibited. If the adding of a toxic substance to one food may be harmful, but harmless when added to another food in limited quantities fixed by a predetermined tolerance,

we are of the opinion that the Secretary is empowered to permit its use in the latter instance. The Secretary at one time seemed of the same opinion. In the Food and Drug Administration Regulations promulgated in 1955, a number of coal-tar colors were listed for certification for use in food, drugs and cosmetics. Among these are colors designated as "lakes". The regulations provide that "No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs."<sup>22</sup> We shall not indulge in speculation upon the comparative porosity of egg shell and orange peel. We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food, and we think he was fully empowered to do so.

We are not unmindful of the admonition of the Second Circuit in the *Certified Color Industry* case, *supra*, that:

"Now that their toxicity has been amply demonstrated it would be unconscionable for any court to require the Secretary to permit their use without the clearest and most uncompromising evidence that usage at certain levels was absolutely safe." 236 F. 2d 870.

With this statement we are in accord. The findings of fact are to be made by the Secretary. Such findings, under Section 701 (f) (3) of the Act,<sup>23</sup> are conclusive if supported by substantial evidence.<sup>24</sup> We again advert to the Secretary's letter to the Chairman of the Committee of the House of Representatives at the time it was considering the 1956 amendment. The Secretary said:

"While the scientific evidence so far available does not establish what the lowest safe dosage

<sup>22</sup> 20 F. R. 9554, 21 C. F. R. § 9.3 (c).

<sup>23</sup> 52 Stat. 1055, 21 U. S. C. A. § 371 (f) (3).

<sup>24</sup> See *Byrd v. United States*, 5 Cir. 1946, 154 F. 2d 62.

would be to test animals, neither does it establish a likelihood of injury to man from the use of this color [Red 32] on the exterior of oranges at the levels of use involved. Before final conclusions can be drawn on this point, however, it is necessary to conduct adequate scientific studies of chronic toxicity on laboratory animals over their life span, which will involve feeding tests at levels related to the quantities of such externally applied color that might enter man's diet. Such tests and studies will require approximately 3 years. We assume that the industry will make such studies."<sup>25</sup>

Since the Secretary is authorized by Section 702 (a) of the Act<sup>26</sup> to conduct examinations and has a technical staff already familiar with the problem, we think it not amiss, in view of our decision here, that we suggest consideration be given by the Department to continuing or resuming the tests and studies from which the evidence was obtained which was adduced before the departmental hearing.

In the *Certified Color Industry* case, *supra*, the court rejected the Secretary's construction of the word "harmless". It holds that the government need not prove that a coal-tar color is in fact injurious to health but it is enough if it shows that it "might render the article of food injurious," adopting the quoted words from the *Lexington Mill* case. Because, in the quantities tested, the possibility of injury to health was indicated, the court sustained the order. It held that "under the circumstances disclosed in the record" the petitioning manufacturers of coal-tar colors could not require the Secretary to establish tolerances fixing safe levels of use. For this position two reasons were assigned, first that safe levels have not been established,

<sup>25</sup> Hearing, *supra*, p. 3.

<sup>26</sup> 52 Stat. 1056, 21 U. S. C. A. § 372 (a).



and second, the department could not control uses within tolerance limits if such limits were prescribed. In connection with the first of these grounds the court comments that the industry made no investigation as to the effect of the colors at low levels of usage. The record bears out the court's observation, but under the Secretary's construction of the Act the effect of the colors at minimal levels would be immaterial. The inability to control the quantity used is no different, as we see it, in dealing with a coal-tar color than with respect to other toxic or poisonous substances where the Secretary is required to establish tolerances. In any event, as the court in the *Certified Color Industry* case points out, the situation before it was different from the case of a single color such as Red 32 applied to a single use such as the colorings of oranges. Such a case is the one before us.

After a hearing in 1939 Red 32 was found to be harmless and suitable for use in foods, drugs and cosmetics. The situation as presented on this review was briefly and accurately characterized in a letter from the Commissioner of Food and Drugs to Florida Senators and Congressmen written February 8, 1955. In speaking of Red 32 the Commissioner said:

"Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Unless there is evidence that, in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption, the 1939 finding should not be supplanted by a contrary ruling by which such use is prohibited. It may be parenthetically observed that "unsafe" is the yardstick for de-

termining tolerances under Section 406 (a). A determination may be made by the Secretary on his own initiative or upon the petition of any interested person," as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use.

At the outset of this proceeding, upon agreement, a stay order was entered to permit the use of Red 32 in coloring oranges while the proceeding was pending. Except as to duration, the substance of the stay order's provisions is followed in our disposition of the matter.

The order promulgated by Marion B. Folsom, Secretary of Health, Education and Welfare, on November 10, 1955, published in the Federal Register on November 16, 1955, (20 F. R. 8492) will be set aside in so far as said order removes the coal-tar color FD&C Red No. 32 from the list of colors which may be certified for use in coloring the skin of oranges meeting minimum maturity standards prescribed in the State of Florida and Texas; *provided*, that nothing herein or in the judgment of this Court entered pursuant hereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use in food, drugs and cosmetics but shall operate to authorize the certification of batches of said color conforming to the specifications for the color appearing at 21 C. F. R. 135.3 (1949 ed.) for the purpose of coloring the skin of mature oranges only; *provided further*, that the Secretary shall be required to certify only sufficient batches of FD&C Red No. 32 as may be necessary to color the skin of mature oranges from time to time; *provided further*, that the certificates issued for batches of FD&C Red

<sup>11</sup> 52 Stat. 1055, 21 U. S. C. A. § 371 (e).

No. 32 may be limited by their certificate for use in coloring mature oranges only; *and provided further*, that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of whether the use of Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined.

Judgment accordingly will be entered setting aside in part, as herein set forth, the aforesaid order of the Secretary.

HUTCHESON, Chief Judge, Dissenting:

I am of the clear opinion that the result reached and the conclusions stated by the majority are unwarranted in law, and also, with respect to the findings of the Secretary of Agriculture, represent a case of judicial fiatting which, though it has sometimes found favor in other courts (Cf. *Quaker Oats v. Security*, 129 F. (2) 76, reversed 318 U. S. 218), has not until now found favor here. Cf. *Byrd v. U. S.*, 154 F. (2) 62.

Because I am of this opinion, I feel constrained not only to note my dissent but to point out as briefly and as effectively as I can the patent errors on which the opinion proceeds. Because, too, it is clear to me that, while certainly presenting matters material for legislative consideration, it as certainly does not present matters material to the determination of the issue presented here, which is not what the law ought to be but what it is, I pass, with no more than comment, the basic assumption of the opinion, that the effect upon the future of the industry of our construction of the statute is the controlling consideration

in this case, to go at once to the controlling issues which are presented for decision here.

The first of these, as stated on page 12 of the majority opinion, is whether the questions presented for our review are the identical questions which were decided by the Second Circuit in the *Certified Color Industry Committee v. Secretary of Health, Education and Welfare* (2 Cir) 1956, 236 F (2) 866.

The second, as the majority opinion states it on page 15 is "whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color, designated as FD&C Red #32, which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges, and, if so required or permitted and if it be determined that there is such a minimum, should the Secretary be required to list and certify such color for such uses".

The third and last, as stated on page 24 of the majority opinion, is whether "If it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required".

I take up these questions in turn to say of the first that I not only find myself in complete agreement with the respondent's position that the decision in the *Certified Color* case is in point, is correct, and should be followed here, but I find completely unconvincing the arguments of the majority in support of its contrary view, that the case is not in point. Indeed, it seems to me that the fact alone that the orange industry was not a party to the appeal in the *Certified Color* case is, from the standpoint of that case as a precedent, as completely insubstantial as the classic



difference claimed to exist between a white and a black horse case.

In short, the test of what was at issue and decided in, and what was the effect of, the decision in the *Certified Color* case, as compared to this one, is to be found in a resort to the opinion in that case. Such a resort will show that the precise question here argued, the meaning and effect of the statute, was determined not with particular reference to the nature and character of the business of particular appellants but upon the basis of a construction of the present statute as compared to former statutes, in the light of the decisions construing and applying them. With deference, the majority has completely misread and misapplied the statement in the opinion in the *Certified Color* case at p. 871, "*Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing*" (emphasis supplied).

In making this statement, the court was not, as the majority in this case seems to think it was, stating that, as applied to oranges, *the construction of the statute under review and the duty of the secretary under it* would be different from the construction of the statute and the duty of the secretary as applied to products generally. In making the statement the court was stating correctly that, viewed from the standpoint of legislative relief by amendment, the problem presented was different from the one presented to the secretary in proceeding under, and the courts in construing, the statute before it was amended. The court was not at all suggesting that the existing statute gave the secretary any different discretion or authority in respect to oranges than in respect to other products. To have so held would have been in

effect to hold that the statute under review here gave the secretary authority in his discretion to consider and determine, product by product, whether he could and should establish tolerances, and this in the face of a statute containing no such language and differently construed both by the Executive or the Legislative branch.

In its treatment of the second question, the majority, acting under the influence of the same idea which dictated its rejection of the result and the reasoning in the *Certified Color* case, that the situation and needs of the Texas and Florida orange industry make a special case out of their complaint and requires a construction of the statute based not upon the language used but upon general legislative considerations as to what such an act ought to provide, draws for the support of its view upon the *Lexington Mill* case, *U. S. v. Lexington Mill & Elev. Co.*, 232 U. S. 399, decided under an entirely different statute, that of 1906, and containing entirely different provisions from those under construction here. It seems clear to me that no sound reason is presented, and no support is found in either the language, the legislative history of the statute under construction, or the authorities cited, for the view of the majority that the Secretary's finding, quoted fully with approval in the *Certified Color* case at p. 871, was wrong and must be set aside.

Finally, while the answer of the majority, to the third and final question, whether the needs of the industry can be taken care of without additional legislation, that it can be, follows naturally enough from what has gone before, it seems clear to me that it is nothing more than a complete tour de force, the substitution of judicial for congressional legislation. Though the Executive and Legislative branches of the

government have determined that the 1956 amendment to Sec. 402 (b) was necessary in order to give the secretary the power to determine tolerances as to coal tar products, the court, differing with both, has held that it can and should by its order in effect say, we will construe the statute, and by order give effect to our construction, so as to make unnecessary, indeed useless, the 1956 amendment or any future congressional legislation, and with the Secretary thus panoplied in the judicial fiat as to his authority under the statute before its amendment, and compelled by the judicial order to give that fiat effect, Congress, the Secretary and the Texas and Florida Industries need trouble themselves no more, but, resting securely upon the judicial legislation and order, they may all go about their business in the future untroubled and undisturbed.

It is one thing for a court to construe a statute. It is quite another for it to rewrite it. I respectfully dissent from what I regard here not as a construction but a rewriting of the statute.

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#### JUDGMENT

Extract from the Minutes of July 12, 1957.

No. 15934

FLORIDA CITRUS EXCHANGE, ET AL.

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE

This cause came on to be heard on the petition of Florida Citrus Exchange, and others, for review of an order of the Secretary of Health, Education and

Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, it is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"HUTCHESON, Chief Judge, dissenting."

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**JUDGMENT**

Extract from the Minutes of July 12, 1957.

No. 15948

FRANK R. SCHELL

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE

This cause came on to be heard on the petition of Frank R. Schell, for a review of an order of the Secretary of Health, Education and Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"HUTCHESON, Chief Judge, dissenting."



**In the United States Court of Appeals  
for the Fifth Circuit**

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No. 15934

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**FLORIDA CITRUS EXCHANGE, ET AL., APPELLANTS**

**v.**

**M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE, APPELLEE**

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No. 15948

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**FRANK R. SCHELL, APPELLANT**

**v.**

**M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF  
HEALTH, EDUCATION AND WELFARE, APPELLEE**

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**ON PETITIONS FOR REVIEW OF AN ORDER OF THE SECRETARY  
OF HEALTH, EDUCATION AND WELFARE**

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(August 28, 1957)

**ON PETITION FOR REHEARING**

Before HUTCHESON, Chief-Judge, and JONES and  
BROWN, Circuit Judges.

Per Curiam.

*It is ordered*, That the petition for rehearing in the  
above entitled and numbered causes be, and it is,  
hereby denied.

HUTCHESON, Chief Judge, Dissenting.